§ 864.5220 Automated differential cell counter.

(a) *Identification.* An automated differential cell counter is a device used to identify and classify one or more of the formed elements of the blood.

(b) *Classification.* (1) Class II (performance standards) when the device is intended to flag or identify specimens containing abnormal blood cells.

(2) Class III (premarket approval) when the device is intended for other uses, including to count or classify abnormal cells of the blood.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device identified in paragraph (b)(2) of this section. See § 864.3.

[45 FR 60596, Sept. 12, 1980, as amended at 55 FR 23511, June 8, 1990]

§ 864.5240 Automated blood cell diluting apparatus.

(a) *Identification.* An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60596, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.5260 Automated cell-locating device.

(a) *Identification.* An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)

(b) *Classification.* Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5300 Red cell indices device.

(a) *Identification.* A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemo-globin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.

(b) *Classification.* Class II (performance standards).

[45 FR 60597, Sept. 12, 1980]

§ 864.5350 Microsedimentation centrifuge.

(a) *Identification.* A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60598, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994]

§ 864.5400 Coagulation instrument.

(a) *Identification.* A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies.

(b) *Classification.* Class II (performance standards).

[45 FR 60598, Sept. 12, 1980]

§ 864.5425 Multipurpose system for in vitro coagulation studies.

(a) *Identification.* A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

(b) *Classification.* Class II (performance standards).

[45 FR 60599, Sept. 12, 1980]

§ 864.5600 Automated hematocrit instrument.

(a) *Identification.* An automated hematocrit instrument is a fully automated or semi-automated device which may or may not be part of a larger system. This device measures the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and